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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,587	08/12/2009	Ryan Smith Westberry	34029/US/2	8800

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DORSEY & WHITNEY LLP
INTELLECTUAL PROPERTY DEPARTMENT
370 SEVENTEENTH STREET
SUITE 4700
DENVER, CO 80202-5647

EXAMINER	
BABIC, CHRISTOPHER M	
ART UNIT	PAPER NUMBER
1637	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,587	WESTBERRY ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER M. BABIC	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *99-119* is/are pending in the application.

4a) Of the above claim(s) *114-117* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *99-113,118 and 119* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/22/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I, claims 99-113, 118, and 119 in the reply filed on April 30, 2010 is acknowledged. Thus, the restriction requirement is still deemed proper and hereby made FINAL. As such, claim(s) 114-117 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Specification

The disclosure is objected to because of the following informalities: pg. 15, line 30 and pg. 17, line 9 has an incomplete application number.

Appropriate correction is required.

Claim Rejections - 35 USC § 112 - Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 112 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 112 recites the limitation "the nucleic acid amplification reaction" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 99-106, 111, and 112 are rejected under 35 U.S.C. 102(b) as being anticipated by Rubinsky et al. (WO 92/12722 A1; 6 August 1992).

Rubinsky teaches a solution comprising an anti-freeze protein (AFP) and an enzyme; wherein the enzyme retains its activity after at least one freeze-thaw event (pg. 38-46, for example). Specifically, the reference teaches oocyte preservation utilizing a solution comprising: a Type I AFP (pg. 17-24; pg. 41, 40mg/ml) and an enzyme (the oocytes naturally contain enzymes including DNA polymerase; pg. 41, presents evidence that the cells can survive freeze-thaw events). The solution further comprises: glycol, glycerol, buffer (PBS), BSA, glucose (pg. 39, AVS solution).

2. Claims 99-101, 107, and 112 are rejected under 35 U.S.C. 102(e) as being anticipated by Demmer et al. (U.S. 7,132,263 B2).

Demmer teaches a solution comprising an anti-freeze protein (AFP) and an enzyme (pg. abstract; example 3, for example). Specifically, the reference teaches modulating the size of ice crystal formation utilizing a solution comprising: an AFP (pg. example 3) and an enzyme (the *E. coli* host cells naturally contain enzymes including DNA polymerase,). The solution further comprises: buffer @ a pH of 8 (example 3).

With specific regard to the "wherein the enzyme retains its activity after at least one freeze-thaw event" clause, it is initially noted that the teachings of Demmer are silent with regard to enzymatic activity. However, since the Patent Office lacks the laboratory facilities to compare prior art teachings with claimed inventions, prior art that appears to anticipate the claimed invention through a reasoned rationale is applied and the burden is shifted to Applicant to provide evidence to the contrary. Applicant is directed to MPEP 2113 which provides:

" As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith (*In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972)),...,Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product (*In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983))."

First, the Demmer teaches,

"The scope for AFP applications extends from genetically modifying prokaryotic or eukaryotic organisms to produce formerly non-resident AFP proteins, into areas where AFPs are used as additives for cryoprotection. An example of this is molecular biology reagents such as restriction endonucleases, DNA modifying enzymes, DNA polymerases and associated buffers which are sensitive to freeze thaw. Molecular biology reagents which are particularly sensitive to freezing, such as in vitro transcription/translation systems could potentially benefit by the presence of AFPs. Whole cells, such as preparations of Escherichia coli, yeasts, blood platelets, red blood cells, ova and sperm, in addition to multicelluar complexes such as embryos and whole organs, could be protected by the ice restructuring properties of AFPs. (col. 2)

Furthermore that reference expressly demonstrates that the isolated AFPs were successful at increasing freeze tolerance in plants (col. 30).

Thus, the reference expressly suggests utilzing AFPs for cryoprotection of DNA polymerases as well as demonstrates the ability of its enzymes to increase viability of plant tissues exposed to freezing. Demmer appears to teach AFPs with the ability to protect enzymes from freeze-thaw events.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 109 and 110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubinsky et al. (WO 92/12722 A1; 6 August 1992) in view of Carpenter (U.S. 4,806,343).

The teachings of the previously applied reference(s) have been outlined in the above rejections. The previously applied reference(s) do not expressly teach sorbitol or trehalose.

As demonstrated by Carpenter provides, it was well known in the prior art that sorbitol and trehalose were common additives in protein cryoprotectant solution (bottom col. 3).

Thus, in summary, it is submitted that it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of invention to add sorbitol and/or trehalose to the solutions of Rubinsky since the prior art demonstrates reagents as cryoprotectant additives.

2. Claim 113 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neilson et al. (U.S. 5,605,824) in view of Rubinsky et al. (WO 92/12722 A1; 6 August 1992).

Neilson teaches an SSB/PCR composition comprising: DNA polymerase enzymes, dNTPs (bottom col. 13), and an anti-freezing component (bottom col. 18).

Neilson does not expressly teaches an anti-freezing protein.

As noted above, Rubinsky teaches AFP solutions.

Thus, in summary, it is submitted that it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of invention to add the AFP of Rubinsky to the solutions of Neilson since Rubinsky demonstrates their AFP as an effective anti-freezing component.

3. Claims 118 and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubinsky et al. (WO 92/12722 A1; 6 August 1992) in view of Stratagene ("Gene Characterization Kits" 1988).

The methods of the previously applied reference(s) have been outlined in the above rejections. The previously applied reference(s) do not expressly teach kits of reagents.

Stratagene catalog provides a supportive teaching that highlights a motivation to combine reagents into kit format (pg. 39, for example).

In summary, it is submitted that it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the reaction reagents as taught by Rubinsky into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (pg. 39, col. 1, for example).

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure:

Walker et al. (U.S. 6,008,016); Hew et al. (U.S. 6,307,020); both teach anti-freezing proteins.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 814-880-9945. The examiner can normally be reached on Monday-Friday 10:00AM to 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher M. Babic/
Primary Examiner

Art Unit 1637
Technology Center 1600